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REMARKS

This application was filed October 16, 2001.

In an Office Action dated December 2002, claims 2, 5, 7, 9-11 and 20 were indicated as containing allowable subject matter.

An amendment placing the allowable claims in independent form was duly filed in March 2003.

A first status inquiry was filed in October 2003.

A second status inquiry was filed in February 2004, along with an Information Disclosure Statement.

On May 11, 2004, the Patent Office issued a second Office Action on the merits, withdrawing all indications of allowable subject matter and effectively restarting prosecution on the merits.

The May 2004 Office Action

Claims 2, 4-7, 9-15, 23-24, 26-27, 31-32, 34-37, and 39 stand rejected under 35 U.S.C. § 102 as being anticipated by Yanof (US 6,035,228).

Claims 8, 17-20, 25, 28-30, 33, and 38 stand rejected under 35 U.S.C. § 103 as being obvious over Yanof.

Claim 3 stands rejected under 35 U.S.C. § 103 as being unpatentable over Yanof in view of Ergun (US 6,007,243).

The Yanof Patent

The Yanof patent is exemplary of the acknowledged prior art and does not address the presently claimed concepts. Yanof is directed to a general purpose CT scanner and stereotactic arm assembly. The arm assembly 30 is supported on an overhead support arm 32 which is movable in a track 34. The arm assembly includes a base joint or pivot 44 which rotates about a vertical axis. A shoulder joint 48 includes a pivot for rotation about a horizontal axis. An elbow joint permits rotation about another horizontal axis. A forearm joint 56 permits rotation of a knuckle member 58 as indicated by arrow D. A wrist joint 60 permits rotation of a wrist member 62 in a direction marked E. From a combination of resolvers in these various joints, and *a priori* information about the lengths of the various arms and other

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physical information, the computer system determines the location of a surgical instrument guidance device 100.

However, all of this information is still not enough to use the stereotactic arm in a surgical procedure. The arm must further have information about the biopsy needle, drill, pointer, tool guide, or other instrument which is attached to it. Specifically, the system must know the type of tool, the angle and offset of its central axis from the mounting point on the arm, the length of the tool, and the like. Absent such information, the computer system would be unable to correlate the trajectory of the movement of the tool with the diagnostic images. Thus, the Yanof system needs to be educated before every tool is actually used in a surgical procedure.

The Continuing Problem

There are many types of general purpose computer guided surgery systems, such as the Yanof system cited by the Examiner. However, there are also many surgical specialties. The various surgical specialties have specially designed surgical tools for various procedures, variations of the various tools coming from competing surgical tool manufacturers.

The cost of software, surgical tools, machine time on systems such as the Yanof system, and labor are all expensive. Yes, a hospital could purchase all of the specialty software for all of the specialty operations in all of the surgical specialties, assuming the computer system of Yanof is large enough to hold it all. However, such specialty software is very expensive. Moreover, on a general purpose system which may be used for numerous different surgical procedures, some of the expensive software will be rarely used and some, possibly, never used. Moreover, if the specialty software is generic to the tools of more than one manufacturer, or if the surgical procedures can be performed with various models of tools, such as larger scale tools for adult surgery and smaller scale tools for pediatric surgery, then the system must be educated regarding the nature of each tool to be used in an upcoming surgical procedure. Such education is typically done using the scanner/stereotactic arm system and a phantom by taking diagnostic images of the phantom with each of the tools. The physical information about the size and shape of each tool can be

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determined and correlated with the diagnostic images. Such education procedures tie-up valuable scanner time.

There is an additional financial problem - health care costs and health insurance. If a hospital purchases a vast amount of software for the scanner, it needs to pass the costs onto its customers, i.e., its patients and their healthcare providers. Patients and their healthcare providers are increasingly not willing to pay a usage fee based on a massive package of software when only a small portion of it was used to treat the patient.

The Present Solution

The present application proposes to provide a kit for each specialty surgical operation that includes the surgical instruments for performing the operation in a sterile state, and a software upgrade for temporarily upgrading the computer system for the designated operation. The kit is designed for a single use. In this manner, the medical service provider can pay for (lease) the software and tools on a per use basis. The patient and his/her healthcare provider are charged only for use of the software and the use of the tools actually used in the surgery. After the single use, the software is deactivated and the non-sterile tools are thrown away or returned for reprocessing. The reprocessing may include the disposal of consumable instruments or instrument parts, such as scalpel blades and the sterilization and repackaging of reusable and, typically, more expensive surgical instruments such as drills. When a kit for a specific surgery is ordered, the sterilized drill, the tools appropriate to the ordered surgery, surgical appliances such as screws and braces in a sterile condition, and application specific software are loaded into a new kit designated and labeled for the specific surgery.

In this way, a patient and his/her insurer pay only the usage cost for that which was actually used in the surgery. If the kit suppliers owns the scanner as well, the kit price can also include the usage cost of the scanner.

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The Claims Distinguish Patentably
Over the References of Record

Claim 2 calls for an image-guided surgery system which includes a computer that provides minimal user functionality, a software-integrated disposable kit, a tracking system, and a display. Yanof does not teach or fairly suggest a software-integrated disposable kit.

Moreover, claim 2 calls for the kit to include instrumented tools for a preselected surgical procedure and digital medium with application specific software specific to the preselected surgical procedure. Yanof fails to teach or fairly suggest the combination of instrumented tools and an application specific software upgrade. Because Yanof fails to teach or fairly suggest a kit, much less a kit with corresponding surgical tools and software, it is submitted that claim 2 and claims 3-4 dependent therefrom distinguish patentably over the references of record.

Claim 5 calls for deactivating or encrypting a digital medium of a software-integrated disposable kit against reuse at the end of a surgical procedure. Although the Examiner has asserted that Yanof anticipates claim 5, he has failed to explain how or where he finds such a means in Yanof. Indeed, it is submitted that Yanof fails to disclose such a deactivating or encrypting means. Accordingly, it is submitted that claim 5 and claims 6 and 12-15 dependent therefrom are not anticipated by and distinguish patentably and unobviously over the references of record.

Claim 7 calls for the combination of an integrated computer and software-integrated, single-use, surgical procedure specific kit. Yanof fails to disclose or fairly suggest such a single use kit.

Moreover, claim 7 calls for the kit to include a label, surgical tools for the preselected surgical procedure in sterile packaging, other accessories for the preselected surgical procedure in sterile packaging, a user input device, and a disposable, one-time use digital medium. Yanof does not disclose such a label, such surgical tools in sterile packaging, such other devices, or such one-time use digital medium. Nor does Yanof suggest such items for the preselected procedure conveniently assembled in a kit. Accordingly, it is submitted that claim 7 is not anticipated by Yanof. Moreover, Yanof makes no suggestion of a one-time use digital medium. There is no suggestion that the software in the Yanof system is

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usable anything other than multiple times. Still further, Yanof fails to provide any motivation for some of the software being reusable and other parts of the software to be one-time use. Accordingly, it is submitted that claim 7 and claim 8 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 9 calls for an image-guided surgery system including a computer, a software-integrated kit, a tracking system, and a display. Yanof fails to disclose a software-integrated kit.

Moreover, claim 9 calls for the kit to include a digital medium which includes a pre-programmed, one-time use application specific software module and a preprogrammed software module describing the surgical tools, implants, or other accessories. Yanof does not disclose a digital medium with a combination of one-time use application specific software and a preprogrammed description of tools, much less the surgical tools which come in the same kit. Accordingly, it is submitted that claim 9 is not anticipated by and distinguishes patentably and unobviously over the references of record.

Claim 10 calls for a combination of a computer and software-integrated one-time use kits. The kits include surgical instruments and a digital medium that includes preprogrammed software describing dimensional specifications of each of the tools in the kit, along with any probes, guides, or other instrumented accessories contained in the kit. Yanof does not disclose a software integrated one-time use kit. Moreover, Yanof does not suggest the combination of surgical tools and a digital medium which describes the tools and other components contained in the kit. Accordingly, it is submitted that claim 10 is not anticipated by and distinguishes patentably and unobviously over the references of record.

Claim 11 calls for an image-guided surgery system including an integrated computer, software-integrated kits, a tracking system, and a display. Yanof does not disclose software-integrated kits. Moreover, the kits are required to include a digital medium which is preprogrammed with software of 3D virtual representations, images, or information of instrumented surgical tools, accessories, implants, and any associated hardware contained in said kit used to create 3D virtual representations of the surgical tools in the images on the display. Yanof does not disclose a kit with software for creating 3D virtual representations of surgical tools.

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Accordingly, it is submitted that claim 11 is not anticipated by and distinguishes patentably and unobviously over the references of record.

Claim 20 calls for a method of image-guided surgery which involves the use of a one-time use surgical application specific kit that contains a digital medium and surgical tools and accessories. Yanof does not disclose such a kit. Further, claim 20 calls for removing digital medium from the kit at a surgical site and inserting it into the computer. Yanof makes no suggestion of loading software into its computer at the surgical site, much less loading augmenting software.

Claim 20 further calls for deactivating or encrypting the digital medium against reuse after the surgical procedure. Yanof makes no suggestion of deactivating or encrypting its software against reuse. Accordingly, it is submitted that claim 20 and claims 17-19, 21, and 22 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 23 is directed to a method of image-guided surgery which includes providing a kit that includes instrumented surgical tools and accessories and a digital medium which is preprogrammed with a portion of a graphics processing program and information concerning the surgical tools and accessories. Yanof does not disclose providing a kit. Claim 23 further calls for, at the surgical site, removing the digital medium from the kit and inserting it into the processor. Yanof does not disclose inserting a digital medium into its computer at the surgical site. Rather, it appears that the software of the Yanof system would be fully loaded well before any surgical procedures. Moreover, Yanof fails to suggest loading software specific to instruments contained in a kit. Accordingly, it is submitted that claim 23 and claims 24-29 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 30 is directed to a surgical kit. Yanof does not disclose a surgical kit. Moreover, claim 30 calls for instrumented surgical tools. In Yanof, the surgical tools are not instrumented. Rather than using instrumentation to determine the position and location of the tools, Yanof uses resolvers in the joints of the stereotactic arm. Moreover, Yanof does not suggest upgrading its computer system with descriptions and improved functionality for a surgical procedure, particularly a

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surgical procedure identified on the label of the kit. Accordingly, it is submitted that claim 30 distinguishes patentably and unobviously over the references of record.

Claim 31 is directed to an image-guided surgery system including a processor which is preprogrammed with less than all of the software for a surgical procedure, and a digital medium preprogrammed with a remaining portion of the software. Accordingly, it is submitted that Yanof does not anticipate claim 31 and that claims 31 and 32-37 dependent therefrom distinguish patentably and unobviously over the references of record.

Claim 38 is directed to an image guided surgery system including a single use digital medium. Yanof fails to disclose or fairly suggest a single use digital medium. To the contrary, it is submitted that the software in Yanof is clearly intended for multiple uses. Further, claim 38 calls for a means for disabling the software. Yanof fails to teach or fairly suggest any means for disabling its software. Accordingly, it is submitted that claim 38 distinguishes patentably and unobviously over the references of record.

Claim 39 calls for providing an integrated computer which (1) receives a digital medium and (2) renders the digital medium inoperative. Yanof does not disclose a computer which renders digital medium inoperative. Claim 39 further calls for deactivating or encrypting the digital medium against reuse. Yanof does not disclose and makes no suggestion of such a deactivation. Accordingly, it is submitted that claim 39 is not anticipated by and distinguishes patentably over the references of record.
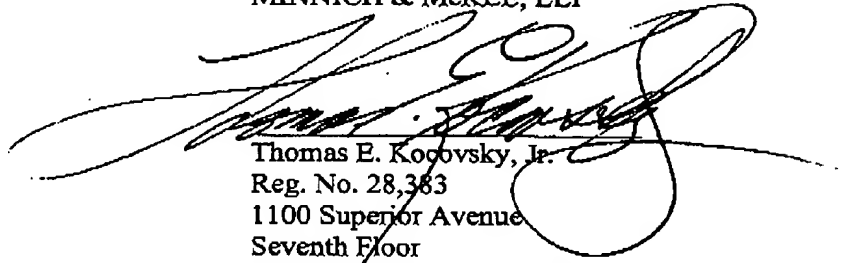
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CONCLUSION

For the reasons set forth above, it is submitted that claims 2-15 and 17-39 (all claims) distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

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